FUJIFILM FUJINON

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510 (k) Summary

APR 22 2009

Date Prepared [21 CFR 807.92(a)(1)]

1/16/2009

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of Fujinon Inc.

Contact / Submitter:
Joseph Azary
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484
Tel: (203) 922-0105
Fax: (203) 922-0130

Sponsor / U.S. Distributor:
Fujinon Inc.
10 High Point Drive
Wayne, NJ 07470
Contact: Gina Walljasper
Telephone: 973-633-5600
FDA Establishment Registration# 2431293

Manufacturer:
Fujinon Corporation
1-324 Uetake-Cho
Kita-Ku, Saitama-Shi
Saitama 331-9624, Japan
Contact: Masayuji Ooyatsu FDA Establishment Registration# 9610875

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Trade Name; Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade or Proprietary Name:	Fujinon EC-450BI5
Common, Usual, or Classification Name:	Colonoscope
Classification:	Class II, 21 CFR 876.1500, FDF

Predicate Device [21 CFR 807.92(a)(3)]

- Fujinon EG-450HL5 (K041903)
- Fujinon EN-450P5/20 (K040048)

Description of the Device [21 CFR 807.92(a)(4)]

The device is intended for the optical visualization of the gastrointestinal tract. This includes the rectum, large and small intestine. It is intended for observation, diagnosis, and endoscopic treatment.

The Fujinon double balloon enteroscopy system utilizes specialized balloons and over-tube to ensure complete positioning of the colonoscope. The tip of the scope can be smoothly inserted to reach the area of diagnosis. This allows for access to hard to reach areas within the bottom portion of the small intestine.

The EC-450BI5 consists of the following portions / parts:

- Control portion – to provide grip for holding the endoscope and for the operation of the endoscope.
- LG Flexible Portion – Contains the light guide, air/water supply tube, suction tube, and cables.
- Bending Portion
- Distal End – Contains objective lens, air/water nozzles, forceps channel.

The EC-450BI5 is used with balloons (BS-1 or BS-2) and an Over-Tube (TS-13101), as well as the balloon pump. The balloon pump, balloons and over-tube were introduced and included as part of the Double Balloon Enteroscopy 510(k).

The EC-450BI5 is used with a Processor (4400) and other peripheral items such as VCR, Television Monitor, and Printers.

Intended Use [21 CFR 807.92(a)(5)]

The device is intended for the optical visualization of the gastrointestinal tract. This includes the rectum, large and small intestine. It is intended for observation, diagnosis, and endoscopic treatment.

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Technological Characteristics [21 CFR 807.92(a)(6)]

Fujinon, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device has the **same** indications for use, material composition, characteristics, reprocessing/sterilization method as the predicate. The subject device uses the same processor and peripherals as the predicate device.

The main difference is the use of a colonoscope for with the double balloon enteroscopy accessories or retrograde application of the double balloon enteroscopy system.

Performance Data [21 CFR 807.92(b)(1)]

The materials in the endoscope are identical to the materials used in the predicate device. Additionally, the device contains the same electrical configurations as the predicate devices.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fujinon, Inc.
% Mr. Joseph M. Azary
Orchid Design
80 Shelton Technology Center
Shelton CT 06484

APR 22 2009

Re: K090116
Trade/Device Name: Fujinon EC-450BI5
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, FED
Dated: January 16, 2009
Received: January 23, 2009

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

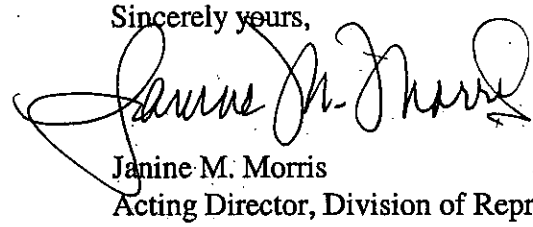
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090116

Device Name: Fujinon EC-450BI5

The device is intended for the optical visualization of the gastrointestinal tract. This includes the rectum, large and small intestines. It is intended for observation, diagnosis, and endoscopic treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ___X_____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090116